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EXAMINER

PATTERSON, CHARLES L JR

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

DATE MAILED: 12/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,072

Applicant(s)

CANFIELD, WILLIAM M.

Examiner

Charles L. Patterson, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/5/01, 6/11/02, 9/16/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25-32, 35-44, 47-58 and 63-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/635,872. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are claiming the same thing as 09/635,872. The other application claims a method of modifying a lysosomal hydrolase using an N-acetylglucosamine-1-phosphotransferase that comprises SEQ ID NO:1-3. The instant claims are drawn to the same thing except that there is a purity requirement in them. It is maintained that the enzyme of 09/635,872 are of the purity claimed in the instant claims, absent convincing proof to the contrary. The purification is taught in the paragraph spanning pages 14 and 15 of the instant specification.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 29, 30-32, 39, 41-46, 50-55, 60 and 62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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✓ ✓ Claims 29, 41 and 53 is confusing and apparently incorrect in the recitation of "N-acetylgalactosamine-6-sulfatase" on line 3, which should apparently be "N-acetylglactosamine-6-sulfatase".

✓ ~~NO NO NO~~ ✓ ✓ Claims 30, 39, 42, 45, 46, 50-52, 60 and 62 are confusing and apparently incorrect in the recitation of " α -N-Acetylglucosamindase", which apparently should be " α -N-Acetylglucosaminidase".

~~NO~~ ✓ ✓ ✓ ✓ ✓ ✓ Claim 39 is indefinite in the recitation of "said modified lysosomal hydrolases", which lacks antecedent basis. The claim is also incorrect in the recitation of "hydrolases" on line 4, which should be "hydrolase".

✓ ✓ ✓ ✓ ✓ ✓ Claims 31, 32, 43, 44, 54 and 55 are confusing and indefinite in the recitation of "which has a". Apparently "which" should be omitted.

Claim 50 is incorrect in the recitation of "hydrolases" on line 7, which should be "hydrolase".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 34, 59 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims recite "the α and β subunits [of N-acetylglucosamine-1-phosphotransferase] are encoded by a DNA molecule comprising nucleotides 133-3627 of SEQ ID NO:20; and the γ subunit is encoded by a DNA molecule comprising nucleotides 296 to 941 of SEQ ID NO:5". The speci-

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fication apparently does not teach anything about residues 133-3617 of SEQ ID NO:20 and teaches on page 18, lines 6-7 that "the γ -subunit is shown in nucleotides 96-941 of SEQ ID NO:5". Since the instant claims were filed after the specification the recitations in the claims is deemed to be new matter.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 25-32, 35-44, 47-58 and 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Kornfeld, et al. (BW). Kornfeld, et al. teach that lysosomal enzymes must be phosphorylated by mannose 6-phosphate in order to be recognized by the receptors in the lysosomal membrane and thus be transported inside. They further teach that two enzymes are involved, first N-acetylglucosamine-1-phosphotransferase and then N-acetylglucosamine-1-phosphodiester α -N-acetylglucosaminidase and they teach the purification of N-acetylglucosamine-1-phosphotransferase 670,000-fold using a monoclonal antibody. It would have been obvious to one of ordinary skill in the art to phosphorylate lysosomal hydrolases using these two enzymes, absent unexpected results. The other requirements of the instant claims would have been obvious, absent convincing proof to the contrary. The motivation would have been to study the uptake of the enzyme into the lysosome and/or the effect of lysosomal diseases. It is noted that claims containing specific sequences have not been rejected because the examiner has been unable to find

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the sequences in the prior art. However, see the 35 USC § 112 first paragraph rejection *supra*.


Claims 25-32, 35-44, 47-58 and 63-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Kornfeld (AY-2 or AZ-2) or Cuozzo (AX) in view of Bao, et al. (AZ). The primary references teach that lysosomal enzymes must be phosphorylated by mannose 6-phosphate in order to be recognized by the receptors in the lysosomal membrane and thus be transported inside. They further teach that two enzymes are involved, first N-acetylglucosamine-1-phosphotransferase and then N-acetylglucosamine-1-phosphodiester α -N-acetylglucosaminidase. Bao, et al. teach a method of purifying the N-acetylglucosamine-1-phosphotransferase 480,000-fold by the use of a monoclonal antibody. It would have been obvious to one of ordinary skill in the art to phosphorylate lysosomal hydrolases using these two enzymes, absent unexpected results. The other requirements of the instant claims would have been obvious, absent convincing proof to the contrary. The motivation would have been to study the uptake of the enzyme into the lysosome and/or the effect of lysosomal diseases. It is noted that claims containing specific sequences have not been rejected because the examiner has been unable to find the sequences in the prior art. However, see the 35 USC § 112 first paragraph rejection *supra*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles L. Patterson, Jr., PhD, whose telephone number is 703-308-1834. The examiner can normally be reached on Monday - Friday, 7:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Charles L. Patterson, Jr.
Primary Examiner
Art Unit 1652

Patterson
November 29, 2002